



FDA Requirements for Plasma Components

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Source Plasma

For injectables:

21 CFR 640.69(b)

- Freeze immediately
- Store at a temperature no warmer than -20°C

21 CFR 610.53

- Expiration is 10 years

21 CFR 600.15

- Ship at -5°C or colder

Source Plasma

For non-injectables:

21 CFR 640.69(b)

- Freeze and store according to intended use of final product

Source Plasma Liquid

For non-injectables:

21 CFR 640.74(b)(2)

- Store at 10C or colder

21 CFR 600.15

- Ship at 10C or colder

Fresh Frozen Plasma/Cryo

21 CFR 640.34(b)

- Place in freezer w/in 8 hrs or w/in time frame specified in the directions for use for the blood collecting, processing and storage system
- Store at -18°C or colder

21 CFR 640.54(a)(2)

- Prepare cryoprecipitated AHF

continued

21 CFR 610.53

- Expiration is 1 year (12 months) from date of collection

21 CFR 600.15

- Ship at -18°C or colder

Recovered Plasma

- Freeze
- Store
- Ship

